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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD. and ACTELION PHARMACEUTICALS US, INC.

Plaintiffs,

Civil Action No. 2:19-12984 (BRM)(DEA)

(Filed Electronically)

1 Idillicit

v.

NATCO PHARMA LIMITED Defendant.

CONSENT JUDGMENT AND ORDER

WHEREAS, this action for patent infringement ("the Litigation") was brought by Plaintiffs Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc. ("Actelion") against Defendant Natco Pharma Limited ("Natco" or "Defendant" and, together with Actelion, "the Parties") for infringement of United States Patent No. 8,309,126 ("the '126 patent");

WHEREAS, Actelion currently markets in the United States, pursuant to New Drug Application No. 209279, bosentan tablets for oral suspension, 32 mg, under the trade name TRACLEER® (the "Tracleer Product");

WHEREAS, Actelion's commencement of the Litigation was based on its receipt of notice from Natco that it had filed with the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 213154 (the "Natco ANDA") containing a "paragraph IV certification" with respect to the '126 patent and seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States of generic versions of bosentan tablets for oral suspension, 32 mg (the "Natco Product"), prior to the expiration of the '126 patent;

WHEREAS, Natco agrees that Claims 4, 6, 7, 8, and 9 of the `126 patent are valid and enforceable with respect to the manufacture, use, offer for sale, sale, and importation of the Natco Product in the United States;

WHEREAS, Natco agrees that Natco's ANDA submission and the commercial manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States of the Natco Product before the expiration of the '126 patent would constitute acts of infringement of Claims 4, 6, 7, 8, and 9 of the '126 patent ("Asserted Claims");

WHEREAS, the Parties desire to avoid substantial litigation costs that would otherwise be incurred and conserve the Court's resources by resolving the Litigation, including appeals therefrom;

WHEREAS, Natco and Actelion have agreed to resolve this litigation, including the right of appeal, for good and valuable consideration recognized by the parties;

WHEREAS, the Parties have agreed to terminate the pending litigation by the entry of this Judgment and Order; and

WHEREAS, the Parties now consent to this Judgment and Order.

The Court, upon the consent and request of the Parties, and upon due consideration and for good cause shown, issues the following Consent Judgment and Dismissal Order.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

- 1. Subject matter jurisdiction, personal jurisdiction, and venue are all proper in this Court.
- 2. Natco's ANDA submission and the commercial manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States of the Natco Product before the expiration of the '126 patent would constitute acts of infringement of the Asserted Claims.
 - 3. The Asserted Claims are valid and enforceable.
- 4. Absent a license from Actelion, the manufacture, use, offer for sale, sale, or import of the Natco Product in the United States would constitute infringement of the Asserted Claims.
- 5. Natco and its Affiliates are hereby enjoined from manufacturing, using, offering for sale, selling in the United States, or importing into the United States, the Natco Product until the expiration of the '126 Patent, including any patent term extensions and/or patent term adjustments and during the period of any associated exclusivity, other than as recognized by the parties.
- 6. All affirmative defenses, claims and counterclaims in this action are hereby dismissed without prejudice.
- 7. Each party shall bear its own fees and costs in connection with this action, including attorneys' fees.
- 8. The Parties waive all right to appeal or otherwise move for relief from this Judgment and Order.
- 9. This Court shall retain jurisdiction of this action and over the Parties for purposes of enforcement of the provisions of this Judgment and Order.

IT IS SO ORDERED, this 2019

Hon. Brian R. Martinotti, U.S.D.J.

By: <u>s/ Keith J. Miller</u>
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